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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,264	01/14/2002	Lynette Fouser	22058-532	4514

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Ivor R. Elrifi
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY AND POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,264	FOUSER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 18 in part, and 19, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, a kit comprising the nucleic acid, and a method of producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 12-16, and 18 in part, drawn to a purified polypeptide, the fusion protein thereof, a pharmaceutical composition thereof, and a kit comprising the polypeptide, classified in class 530, subclass 350.

III. Claims 17, and 18 in part, drawn to an antibody, classified in class 530, subclass 387.9.

IV. Claim 20, 30 and 31, drawn to a method of detecting the nucleic acid with a probe or primer, and a method for determining the presence of a disease by measuring the nucleic acid, classified in class 435, subclass 6.

V. Claim 21, 28 and 29, drawn to a method of detecting the polypeptide, and a method for determining the presence of a disease by measuring the polypeptide, classified in class 435, subclass 7.1.

VI. Claim 22, drawn to a method of modulating the activity of the polypeptide with a compound binding to said polypeptide, classification depending upon the chemical entity of the compound.

VII. Claims 23 and 24, drawn to a method of modulating the activity of IL-22 with the polypeptide, classified in class 514, subclass 2.

VIII. Claim 25, drawn to a method for screening for a modulator of activity by binding assay, classified in class 435, subclass 7.1.

IX. Claims 26 and 27, drawn to a method for screening for a modulator of activity using recombinant test animal, classified in class 800, subclass 3.

X. Claims 32 and 33, 38, 39 in part, 40, 41, 44, 45 in part, 46, 47, 50, 51 in part, 52, and 55-60, drawn to a method of treating or preventing a pathological condition,

rheumatoid arthritis, multiple sclerosis, a method of modulating vascular smooth muscle cell proliferation, and a method of treating or preventing inflammation by *increasing* the amount of a CRF2-12 using said *polypeptide*, classified in class 424, subclass 85.1.

XI. Claims 11, 34 and 35, 38, 39 in part, 40, 41, 44, 45 in part, 46, 47, 50, 51 in part, 52, 55-59 and 61, drawn to a pharmaceutical composition comprising the nucleic acid, a method of treating or preventing an immune disorder, rheumatoid arthritis, multiple sclerosis, a method of modulating vascular smooth muscle cell proliferation, and a method of treating or preventing inflammation by *increasing* the amount of a CRF2-12 using the *nucleic acid*, classified in class 514, subclass 44.

XII. Claims 36 and 37, 38, 39 in part, 40, 42-44, 45 in part, 46, 48-50, 51 in part, 53-58, 62 and 63, drawn to a method of treating or preventing a pathological condition, rheumatoid arthritis, multiple sclerosis, a method of modulating vascular smooth muscle cell proliferation, and a method of treating or preventing inflammation by *decreasing* the amount of a CRF2-12 using an antibody therefor, classified in class 424, subclass 139.1.

XIII. Claims 38, 39 in part, 40, 42, 44, 45 in part, 46, 48, 50, 51 in part, 53, 55-58, 62 and 64, drawn to a method of treating rheumatoid arthritis, multiple sclerosis, a method of modulating vascular smooth muscle cell proliferation, and a method of treating or preventing inflammation by *decreasing* the amount of a CRF2-12 using the *nucleic acid*, *anti-sense* nucleic acid, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and proteins are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification

from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention III because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention III because the antibody may be neither made by nor used in the method.

The nucleic acid of Invention I is related to Inventions IV and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the recombinant production of the polypeptide of Invention II.

Inventions I is distinct from and unrelated to Inventions V-X, XII and XIII, wherein the nucleic acid of Invention I can be neither made by nor used in the method of Inventions V-X, XII and XIII, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention II is distinct from and unrelated to Inventions IV, V, IX, and XI-XIII, wherein the polypeptide of Invention II is neither made by nor used in the methods of Inventions IV, V, IX, and XI-XIII, and wherein each does not require the other.

Invention II is related to Inventions VI-VIII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention III.

The antibody of Invention III is distinct from and unrelated to Inventions IV-XI and XIII, wherein the antibody of Invention III is neither made by nor used in the methods of Inventions IV-XI and XIII, and wherein each does not require the other.

Invention III is related to Invention XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention II.

Inventions VI-XIII are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further restriction is required under 35 U.S.C. 121:

A. One specific nucleotide sequence and its corresponding amino acid sequence with SEQ ID NO:, i.e. SEQ ID NO:1 and 2; 3 and 4; 5 and 6; 11 and 12.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - XIII, one from Group A, even though the requirement is traversed. Applicant is advised that neither I - XVI nor A and B are species election requirements; rather, each of I – XIII and A is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DJ
6/12/03